UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,890	12/27/2000	Glen J. Anderson	1814	9039

30408 7590 04/05/2005

GATEWAY, INC.
ATTN: PATENT ATTORNEY
610 GATEWAY DR.
MAIL DROP Y-04
N. SIOUX CITY, SD 57049

EXAMINER	
ZHOU, SHUBO	
ART UNIT	**PAPER NUMBER**
1631	

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/751,890	ANDERSON, GLEN J.	
	Examiner	Art Unit	
	Shubo (Joe) Zhou	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/26/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-18 are currently pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed 4/26/01 has been entered and considered. Document 14 is lined through on the PTO-1449 because no publication date is provided. The document, however, has been considered. Initialed copy of the form PTO-1449 is enclosed with this action. It is noted that, on the PTO-1449, "December 27, 1000" is listed as the filing date for this application, which apparently contains a typographical error and has been corrected by the Office to be "December 27, 2000".

Specification

The specification is objected to because of the following:

It appears that trademark is used in this application, such as GENECHIP™ (registered by AFFYMETRIX, INC. CORPORATION, 3380 Central Expressway, Santa Clara, CALIFORNIA 95051) on page 8. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections-35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for partially sequencing the genome of a human individual, does not reasonably provide enablement for sequencing the human genome into its complete DNA sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are drawn to a method of providing and updating customized health care information comprising sequencing the genome of an individual to its DNA sequence. The term "individual" in the claim reads on a human individual. Further, "sequencing said genome into its DNA sequence" recited in the claims is interpreted to comprise completely sequencing and partially sequencing the genome. Thus, one embodiment of the claimed invention is sequencing the genome of a human individual to its complete DNA sequence.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)), the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of

experimentation; (b) the amount of guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the predictability of the prior art; (g) the breadth of the claims; and (h) the relative skill in the art. The factors are analyzed for the instant case as follows:

(a) In the instant case, the amount of experimentation required by a skilled artisan in order to practice sequencing the genome of a human individual to its complete DNA sequence would require an unpredictable amount of experimentation for the following reasons:

(b) One embodiment of the claimed method comprises completely sequencing the genome of a human individual. However, there is no guidance in the instant specification that teaches the skilled artisan how to completely sequence a human genome.

(c) The instant application does not present any working examples wherein a human genome is completely sequenced.

(d)-(f) The nature of the invention, a method of providing and updating customized health care information to an individual comprising completely sequencing the genome of the individual is complex. Human genome sequencing, at the time the instant invention was made, was a consorted international project combining the most advanced technologies of the world. See Brown, Kathryn, Scientific American, July 2000, pages 50-55. And yet, as admitted in the specification on page 3, only 90% of the human genome could be sequenced as of June 2000. As a matter of fact, even in 2001, in the first draft of the sequenced human genome by the International Human Genome Sequencing Consortium, only 90% of the gene-rich euchromatic portion of the genome had been sequenced, and only about a quarter of the whole genome was considered finished due to the limitation of the technology. See Bork et al., page 818, left column

(Nature, Vol. 409, pages 818-820, 2001). Bork et al. also state that "there are regions, often highly repetitive, that are difficult or impossible to clone (one of the initial steps in a sequencing project) or sequence with current technology." See page 818, "Box 1". Clearly, the prior art is unpredictable with regards to sequencing a human genome into its complete DNA sequence including the un-sequencable regions. The prior art does not teach how to sequence these regions.

(g)-(h) The claims, drawn to method of providing and updating health care information comprising sequencing the genome of an individual, are broad. The level of skill of those in the art who practice sequencing a human genome is high.

The skilled practitioner would first turn to the instant specification for guidance in practice of completely sequencing the genome of a human individual. However, the specification does not provide sufficient guidance of practicing the method as claimed. As such, the skilled practitioner would turn to the prior art for such guidance. However, the prior art does not teach how to do so. Finally, the practitioner would turn to trial and error experimentation in trying to sequence the complete genome of a human individual, without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the limitation "sequencing said genome into its DNA sequence" in claim 1, claims 17-18, and their independent claims are unclear. It is not clear whether the genome is completely sequenced to its DNA sequence, or, the limitation also encompasses partially sequencing the genome. If partially sequencing is included, it is not clear how much sequencing of the genome is minimumly required as partial sequencing.

The meaning of the phrase "updating said searching for at least one additional medical condition associated with said DNA sequence" in claim 4 is unclear because it is not clear how often (e.g. once a year, a month, or a day) the searching is to be updated. The phrase renders the claim indefinite.

The phrase "said tracking" in claim 6 lacks clear antecedent basis and renders the claim indefinite. Claim 6 depends from claim 5, which in turn, indirectly depends from claim 1. There is a step of "tracking for additional information relating to said at least one medical condition" in claim 1, and a step of "tracking discoveries of genetic variations associated with said at leas one additional medical condition" in claim 5. Thus, claim 5 actually comprises two different "tracking" steps. It is unclear which tracking step is meant in claim 6 by "said tracking".

The phrase "said information" in claim 10 lacks clear antecedent basis and renders the claim indefinite. Claim 10 depends from claim 1, which recites the term "information" multiple times with apparent different meanings. The preamble of claim 1 recites "health care information"; the 4th and 5th steps of claim 1 recite "information relating to the existence of" at least one medical condition associated with the genome; and the 6th and 7th steps recite "additional information relating to" the at least one medical condition. However, it is unclear which information is meant in claim 10 by "said information".

Similarly, the phrase "said information" in claim 13 and in claim 14 lacks clear antecedent basis and renders the claims indefinite. Claims 13 and 14 depend from claim 1, directly or indirectly, which recites the term "information" multiple times with apparent different meanings. The preamble of claim 1 recites "health care information"; the 4th and 5th steps of claim 1 recite "information relating to the existence of" at least one medical condition associated with the genome; and the 6th and 7th steps recite "additional information relating to" the at least one medical condition. However, it is unclear which information is meant in claims 13 and 14 by "said information".

The phrase "the health specialist" in claim 14 lacks clear antecedent basis. Claim 14 is dependent from claim 11, which, in turn, depends from claim 1. However, neither in claim 1, nor in claim 11 is the phrase "health specialist" recited.

The phrase "said information" in the last step of claim 18 also lacks clear antecedent basis and renders the claim indefinite. The term "information" is recited multiple times in claim 18 prior to the last step including "information related to said conditions" and "information related to said personal data". However, it is unclear which information is meant by "said information" in the last step.

Clarification of the metes and bounds of the claims is requested.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> *A person shall be entitled to a patent unless –*
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 8, 10, 12-13, 16, and 18 are rejected under 35 U.S.C. § 102(a) as being anticipated by Patel et al. (American Journal of Ophthalmology, Vol. 129, pages 258-260, Feb. 2000).

Patel et al. disclose a method of obtaining and providing genetic information for an individual. The method comprises obtaining blood sample from family members of a patient (proband) with unilateral hemangioblastoma and sequencing the three exons of the VHL genes of their genome into DNA sequences. See page 258 and page 260, left column. The sequence of the VHL gene from each family member is analyzed by searching and comparing with the published VHL gene sequence (GenBank accession number 2282064). The VHL sequences of the proband, his father and brother are interpreted to have a deletion of three base pairs which encodes a phenylalanine in the VHL protein, the mutation of which leads to a syndrome referred to as von Hippel-Lindau disease. See page 258, right column, page 259, Figures 1 and 2, and page 260, left column. These read on the steps of "sequencing", "interpreting" and "searching" of claim 1. The fact that the information relating to the existence of a medical condition such as retinal hemangioblastoma is published in this article inherently shows that this information is archived and stored in a storage device by the authors and/or by the publishing company, and that the information is available to everyone including the individuals from whom the DNAs were derived. This reads on the steps of "archiving" and "making information .... available ...." of claim 1. Patel et al. tracked for additional information relating to von Hippel-Lindau disease, and found that the disease also includes an array of tumors in different tissues including spinal cord and cerebellum tumors. See page 260, left column. This reads on the "tracking" step of claim 1. The fact that this additional information relating to the existence of medical condition is

published in this article inherently shows that this information is made available to, and accessible by, everyone including the individuals from whom the DNAs were derived. This reads on the step of "making said additional information accessible by said individual" of claim 1.

It should be pointed out that, as set forth above, the "sequencing" step of claims 1-18 reads on partially sequencing the genome of an individual into its DNA sequence, which is the case in Patel et al., who sequenced part of the genomes of the individuals.

As to claim 2, Patel et al. interpreted the sequences of the individuals by comparing with a GenBank sequence and with databases of known VHL mutations and their phenotypes. See page 260, left column, where Crossey et al. (ref 30) is cited, which discloses correlations of VHL mutations with phenotypes.

As to claim 3, the fact that the interpretation of the VHL sequences in relation to published wild type VHL genes and the association of VHL mutation with von Hippel-Lindau disease is published in this article inherently shows that this interpretation is archived, at least, in this publication.

As to claim 8, the fact that the interpretation of the VHL sequences in relation to published wild type VHL genes and the association of VHL mutation with von Hippel-Lindau disease is published in this article inherently shows that this interpretation is accessible for current and for future analysis.

As to claim 10, since, as set forth above, the phrase "said information" lacks clear antecedent basis, it is interpreted that the information in the claim is the information for the existence of a medical condition associated with the genome of the individuals. Since the sequences of the proband, the father and the brother all show the same mutation of the VHL

gene, i.e. a deletion, the father and brother may have the disease although it was not previously diagnosed. After the sequencing and analysis, Patel et al. detected small tumors from the father and the brother. See page 260, left column. Thus, the information comprises diagnosis, as required in the claim.

As to claim 12, the fact that the additional information relating to the medical condition, i.e. von Hippel-Lindau disease, is published in this article inherently shows that this additional information is archived, at least, in this publication.

As to claim 13, the fact that after the analysis of the sequences and interpretation of the information, the father and brother of the proband, while no tumors were previously diagnosed, were undergone MRI and small tumors were detected, inherently shows that the information of the sequence analysis and association of VHL mutation with von Hippel-Lindau disease has been communicated with health specialists – those who performed the MRI analysis.

As to claims 16 and 18, the method by Patel et al. comprises personal data from the individual proband such as the health information of the father, brother, mother, and paternal grandparents. See page 258, right column, and page 260, left column. Since the father and brother also comprise the same genomic mutation in their VHL genes, the tracking for additional medical conditions also comprises medical conditions associated with their genomes.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-7, 9, 11, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. (American Journal of Ophthalmology, Vol. 129, pages 258-260, Feb. 2000), as applied to claims 1-3, 8, 10, 12-13, 16, and 18 above, in view of Beroud et al. (Nucleic Acids Research, vol. 26, pages 256-258, 1998).

Claims 4-7 and 17 are drawn to a method of providing health care information based on sequencing a genome to its DNA sequence. The method comprises updating the searching for at least one additional medical condition associated with said DNA sequence by tracking discoveries of genetic variations associated with the additional medical conditions.

As applied to claims 1-3, 8, 10, 12-13, 16, and 18 above, Patel et al. disclose a method of providing genetic information based on gene sequencing. While Patel et al. do not explicitly recite the phrase "updating" the searching, Patel et al. state that lifelong follow-up is warranted with this disease, and this case demonstrates the value of DNA testing in patients with ocular findings consistent with von Hippel-Lindau disease in the absence of a recognized family

history. See page 260, left column, last paragraph. This clearly suggests and motivates life long follow up for the disease.

Beround et al. compile the published VHL mutations and their associated medical conditions into a database and provide a computer software to search the database. Beround et al. make the database and software accessible via the internet and world wide web at http://www.umd.necker.fr. See Abstract. Beround et al. indicate that the database would be updated and would be made available through the world wide web. See page 269, right column, and page 270, left column.

One of ordinary skill in the art would have been motivated by Patel et al.'s statements to modify Patel et al's method to update the searching of new variations of the VHL sequence in relations to new phenotypes and tracking new discoveries of VHL mutations associated with medical conditions in order to perform the life-long follow-up referred to by Patel et al. by searching the database of Beround et al. using their computer software because the database comprises all the published VHL variations and their corresponding phenotypes, and it would be updated and available to the public.

This updating of searching, interpretation of the genome for more medical conditions, and tracking for new discoveries of genetic variation of the gene associated with new medical conditions by searching the database of Beround et al. read on the limitation recited in claim 9, i.e. interpretation of the genome for additional medical conditions after the initial search is completed, the limitation in claim 11, i.e. the tracking is done electronically, and the limitation in claim 15, i.e. making the information accessible electronically because the database by Beround et al. and the computer software therewith are provided via the internet.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst Tina Plunkett whose phone number is (571) 272-0549.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as

general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shubo (Joe) Zhou, Ph.D.

Patent Examiner

Ardin H. Marschel 3/16/05

ARDIN H. MARSCHEL
PRIMARY EXAMINER